(1) * * *

Food	Limitation (parts per million)	Use
* * * * *		
Fava beans (cooked canned).	365	Promote color retention.
* * * * *		

* * * * *

Dated: June 15, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–15924 Filed 6–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0033]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane as an antioxidant for high density polyethylene intended for use in food-contact articles. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

DATES: Effective June 29, 1995; written objections by July 31, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 12, 1993 (58 FR 13604), FDA announced that a food additive petition (FAP 3B4358) had been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane as an antioxidant for polyethylene complying with § 177.1520 *Olefin polymers* (21 CFR 177.1520) intended for use in food-contact articles.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that data in the petition support the safe use of the additive only in high density polyethylene with a minimum density of 0.94, and under limited use conditions. Therefore, the use of the additive has been limited in § 178.2010(b) consistent with these conditions.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before July 31, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the ''Limitations'' for the entry ''3,9-Bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1 dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * * * * *
3,9-Bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane (CAS Reg. No. 90498–90–1).	For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520(c), item 1.1 of this chapter. The finished polymer is to be used in contact with food only under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of polyethylene complying with § 177.1520(c) of this chapter, item 2.1, provided that the polymer has a minimum density of 0.94 grams per cubic centimeter and is used in contact with food only under conditions of use D through G described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * * * * *

Dated: June 15, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–15922 Filed 6–28–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 442

[Docket No. 94N–0132]

Antibiotic Drugs; Cefotetan and Cefotetan Disodium Injection; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is technically amending a final rule that appeared in the **Federal Register** of May 25, 1994 (59 FR 26939). The document amended the antibiotic drug regulations to provide for the inclusion of accepted standards for a new bulk form of cefotetan. The agency received a comment on the final rule that pointed out, among other things, that the correct name of the antibiotic is cefotetan disodium. This document corrects those errors.

EFFECTIVE DATE: June 29, 1995.

FOR FURTHER INFORMATION CONTACT: James M. Timper, Center for Drug Evaluation and Research (HFD–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6714.

SUPPLEMENTARY INFORMATION: As published, the final regulation contains errors that may prove to be misleading and are in need of clarification. The name of the antibiotic is ''cefotetan disodium'' not ''cefotetan sodium.'' The calculation for determining cefotetan concentration in the finished dosage form was published incorrectly, and an additional sample preparation, potassium bromide discs, can be used also. Accordingly the agency is amending 21 CFR 442.52 to correct those errors.

List of Subjects in 21 CFR Part 442

Antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 442 is amended as follows:

PART 442—CEPHA ANTIBIOTIC DRUGS

1. The authority citation for 21 CFR part 442 continues to read as follows:

Authority: Sec. 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

2. Section 442.52 is amended by revising paragraphs (b)(1)(iv) and (b)(3) to read as follows:

§ 442.52 Cefotetan.

(b) * * *

(1) * * *

(iv) *Calculation*. Calculate the micrograms of cefotetan per milligram of sample as follows:

$$\text{Micrograms of cefotetan per milligram} = \frac{A_U \times P_S \times V_f \times 1{,}000}{A_S \times V_s}$$

where:

A_U = Area of the cefotetan peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_S = Area of the cefotetan peak in the chromatogram of the cefotetan working standard;

P_S = Cefotetan activity in the cefotetan working standard solution in micrograms per milliliter;

V_f = Volume of flask used to dilute standard; and

V_s = Volume of sample diluted.

* * * * *

(3) *Identity*. Proceed as directed in § 436.211 of this chapter using the potassium bromide discs prepared as described in § 436.211(b)(1) of this chapter or the mineral oil mull prepared as described in § 436.211(b)(2) of this chapter.

Dated: May 9, 1995.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 95–15923 Filed 6–28–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 637

[FHWA Docket No. 94–13]

RIN 2125–AD35

Quality Assurance Procedures for Construction

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is revising its regulations that establish general